

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Bitter Tonic" was false and misleading since, in order to derive benefit from a bitter tonic, it should be used regularly over an extended period, and the article, by reason of its laxative properties, was not suitable for such use; Section 502 (e) (2), the label failed to bear a statement of the quantity or proportion of strychnine in the article, since the label statement, "containing .038 grains of strychnine alkaloid per fluid oz.," was incorrect; Section 502 (f) (1), the article was represented as a stomachic, and the labeling failed to bear adequate directions for use as such; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe methods or duration of administration of the article, since it failed to warn that, when taken frequently or continuously, as was provided by the directions, such use may result in dependence upon laxatives to move the bowels.

DISPOSITION: September 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1809. Misbranding of an unlabeled drug. U. S. v. 1,944 Bottles of an Unlabeled Drug. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16713. Sample No. 4166-H.)

LIBEL FILED: July 26, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 25, 1945, from Camden, N. J., by the Aid Laboratories.

PRODUCT: 1,944 unlabeled 3-ounce bottles of a drug consisting of a solution of epsom salt, iron chloride, a small proportion of a citrate, and a trace of quinine in glycerin and water, at Philadelphia, Pa.

NATURE OF CHARGE: Misbranding, Section 502 (b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and it failed to bear an accurate statement of the quantity of the contents; Section 502 (e) (2), it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f), the article was essentially a laxative, and its labeling failed to bear any directions for use; and it also failed to warn that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article may result in dependence upon laxatives to move the bowels.

DISPOSITION: October 11, 1945. The Union Drug Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for labeling under the supervision of the Federal Security Agency.

1810. Misbranding of BF-1 Tablets. U. S. v. 598 Bottles and 16 Bottles of BF-1 Tablets, and 5,000 leaflets. Default decree of condemnation and destruction. (F. D. C. No. 16712. Sample Nos. 27842-H, 27843-H.)

LIBEL FILED: August 18, 1945, Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of June 23, 1944, and April 2, 1945, by the Vegetrates Co., from Los Angeles, Calif.

PRODUCT: 598 100-tablet bottles and 16 450-tablet bottles of *BF-1 Tablets*, and 5,000 leaflets entitled "Vegetrates," at Seattle, Wash. Examination showed that the product consisted of ground plant material, including senna, alfalfa, starch, Irish moss, dulse, yeast, and parsley.

NATURE OF CHARGE: Misbranding, Section 502 (a), the words "Average Ration," borne on the bottle label, and certain statements in the leaflets, were misleading since they represented and suggested that the article was a food, whereas it was not a food, but a laxative drug; and the following statements in the leaflet were false and misleading since a senna laxative is not capable of producing the benefits claimed: "Use Vegetrates BF-1 and Live, Work, Play Every Day. Don't let restless nights spoil your tomorrows. That glorious feeling of waking up each morning ready to start the day with a song! No putting off appointments, turning down 'dates,' neglecting work because you are 'all in,' have a headache, or feel bad. You, too, can enjoy the sparkling, vibrant freshness each morning by being 'regular.' When that slightest feeling of heaviness, or that 'clogged up' feeling comes, try Vegetrates BF-1, used as directed on label."

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe methods or duration of administration, since the warning appearing on the label, "do not use a laxative continuously as there is a possibility of it becoming habit forming," had been made